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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,468	08/27/2003	Andrew P. Kramer	279.31US2	5369

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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402-0938

EXAMINER

LAYNO, CARL HERNANDZ

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

TJH

Office Action Summary	Application No. 10/649,468	Applicant(s) KRAMER ET AL.	
	Examiner Carl H. Layno <i>Carl H. Layno 8/25/05</i>	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 9, 11, 12, 19 and 20 is/are rejected.
- 7) ☒ Claim(s) 3-8, 10 and 13-18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/27/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for priority filing as a Continuation of U.S Application Serial No. 09/844,256, filed April 27, 2001, now U.S Patent No. 6,628,988.

Information Disclosure Statement

2. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449), which was received by the Office on August 27, 2003. Applicant's foreign patents and publications were not considered since these references were not received by the Examiner. If you wish these references to be considered please submit a hard copy of each.

Drawings

3. Applicant's formal drawings were received by the Office on August 27, 2003 and have been approved by the Examiner.

Specification

4. The disclosure is objected to because of the following informalities:
 - p.1, lines 5-6, the status of U.S Application Serial No. 09/844,256, should be updated to reflect the fact that it is now U.S Patent No. 6,628,988.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 2, 9, 11, 12, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heynen et al (US 6,507,756) in view of Kieval et al (US 5,507,782).

The Heynen et al (US 6,507,756) patent describes an implantable dual chambered pacemaker and associated method of using, which delivers pacing pulses to a patient following a time adaptive AV delay interval. These pacing pulses are meant to alleviate wall stresses in the patient's heart (col.5, lines 23-26 and lines 49-60) as part of a heart remodeling process. Pre-excitation pulses are delivered to the ventricular apex and septum following a modified programmed (shortened AV delay) (col.3, lines 25-27, col.5, lines 23-26). Unlike applicant's claims, however, Heynen et al does not recite the measurement of a V-V interval or equivalent time period for shortening its paced AV delay.

The Kieval et al (US 5,507,782) patent describes an implantable pacemaker system, which also delivers pacing pulses to a patient's heart following an AV delay period. As shown in Fig.7, a pace may be delivered following a shortened calculated sensed AV delay (SAV) period, which is defined as the difference between the monitored AV delay time (AVm) and a ventricular sensed offset (VSO). It is the Examiner's position that this VSO time period is equivalent to the V-V interval claimed by the applicant since VSO has been defined as the difference between an AV escape interval resulting from complete ventricular capture and an AV

Art Unit: 3762

conduction time (i.e. the time difference between an earlier excited ventricular capture and another ventricular site). See col.2, lines 40-54.

To have specified that the AV modifications of Kieval et al (US 5,507,782) be used in the Heynen et al (US 6,507,756) patent would have been an obvious modification since Heynen et al already cites the use of this patent as an example of synchronized AV pacing which may be used in its treatment of HOCM (Hypertrophic Cardiomyopathy) patients (col.3, lines 5-30 of Heynen et al).

In regard to claims 2 and 12, the VSO of the formula: $SAV = AVm - VSO$ in Fig.7 of Kieval et al is considered to be a linear function.

In regard to claim 11, applicant's attention is directed to Fig.4 of Heynen et al which shows the implantable pacemaker 300 comprising A-sense and V-sense circuits 360, V-pace and A-pace pacing channels 114,116, respectively, a controller 330 including AV interval timers 372, escape interval timers 370, and intrinsic interval timers 360, capable of sensing/calculating V-V intervals and AV delay intervals and adjustments (col.12, lines 1-12).

In regard to claims 19 and 20, both the Kieval et al and Heynen et al pacemakers have atrial pacing capabilities in response to sensed or pace atrial events and ventricular capabilities in response to sensed or paced ventricular events since they are DDD/DDDR pacers (col.2, line 5 of Kieval et al and col.1, line 58 of Heynen et al).

Allowable Subject Matter

7. Claims 3-8, 10, and 13-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following references are cited for their pertinent teachings of using pacing circuits to sense and treat stressed areas of the heart:

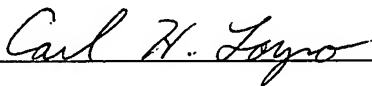
Rosenberg	US 6,314,322
Rosen et al	US 6,868,287
Salo et al	US 6,640,135
Ben-Haim	US 6,317,631
Ben-Haim	US 2002/0045809

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in cursive script, reading "Carl H. Layno", is positioned above a horizontal line.

CARL LAYNO
PRIMARY EXAMINER

CHL
8/25/2005